

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

HSIN LIN,
Plaintiff,
v.
SOLTA MEDICAL, INC.,
Defendant.

Case No. 21-cv-05062-PJH

**ORDER GRANTING IN PART AND
DENYING IN PART DEFENDANT'S
MOTION FOR SUMMARY JUDGMENT**

Re: Dkt. No. 117

Defendant Solta Medical, Inc.'s ("Solta") motion for summary judgment came on for hearing before this court on November 14, 2024. Plaintiff Hsin Lin appeared through her counsel, Jeremy Pollack. Defendant appeared through its counsel, David Norden and Hyung Steele. Having read the papers filed by the parties and carefully considered their arguments and the relevant legal authority, and good cause appearing, the court hereby GRANTS IN PART and DENIES IN PART defendant's motion, for the following reasons.

BACKGROUND

This is a products liability action filed by a California resident, Hsin Lin, against two out-of-state corporations, Solta Medical, Inc. and Bausch Health Americas, Inc. ("BHA") (collectively "defendants"). First Am. Compl., Dkt. 36 ("FAC") ¶¶ 1–3. Plaintiff alleges that she suffered injuries as a result of a laser skin treatment she received in Taiwan that utilized a Thermage CPT device manufactured by defendants. *Id.* ¶¶ 24–30. Plaintiff alleges that in January 2019, her friend put her in touch with a consultant at U Beaute Clinic in Taipei. *Id.* ¶ 25. On January 23, 2019, plaintiff received her treatment and

suffered second-degree burns as a result. Id. ¶¶ 27–30.

On January 21, 2021, plaintiff filed a complaint in the Alameda County Superior Court. Dkt. 1-1. On June 30, 2021, defendants removed the case to this court pursuant to 28 U.S.C. § 1441(a). Dkt. 1. On July 7, 2021, defendants moved to dismiss the case for lack of personal jurisdiction and failure to state a claim. Dkt. 8. On December 6, 2021, the court denied defendants’ motion to dismiss in part and granted plaintiff’s request for jurisdictional discovery. Dkt. 35. The court found that it lacked general jurisdiction over defendants due to insufficient contacts with the forum state, but it deferred ruling on the existence of specific jurisdiction until jurisdictional discovery was conducted. Id. at 7–11. The court also found that plaintiff’s form complaint lacked the specificity to state a claim and granted leave to amend. Id. at 12.

On December 20, 2021, plaintiff filed her first amended complaint. Dkt. 36. Plaintiff asserted three products liability causes of action: (1) defective design, (2) manufacturing defect, and (3) failure to warn. Id. at 8–15. Plaintiff also asserted causes of action for (4) negligence, (5) breach of express warranty, and (6) breach of implied warranty. Id. at 16–20. All claims relate to the allegedly defective Thermage CPT device.

On February 2, 2022, defendants moved to dismiss plaintiff’s FAC for lack of personal jurisdiction. Dkt. 41. On June 21, 2022, the court denied the motion with respect to Solta and granted it with respect to co-defendant Bausch without leave to amend. Dkt. 56. On June 28, 2023, plaintiff filed a second amended complaint stating the same causes of action. Dkt. 70 (“SAC”).

DISCUSSION

A. Legal Standard

Summary judgment is proper where the pleadings, discovery, or affidavits show that there is “no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). Material facts are those “that might affect the outcome of the suit under the governing law”. Anderson v. Liberty Lobby, Inc.,

477 U.S. 242, 248 (1986). A dispute as to a material fact is genuine “if the evidence is such that a reasonable jury could return a verdict for the nonmoving party.” Id. “A ‘*scintilla* of evidence,’ or evidence that is ‘merely colorable’ or ‘not significantly probative,’ is not sufficient to present a genuine issue as to a material fact.” United Steelworkers of Am. v. Phelps Dodge Corp., 865 F.2d 1539, 1542 (9th Cir. 1989) (quoting Anderson, 477 U.S. at 249–50).

Where the moving party will have the burden of proof at trial, it must affirmatively demonstrate that no reasonable trier of fact could find other than for the moving party. Soremekun v. Thrifty Payless, Inc., 509 F.3d 978, 984 (9th Cir. 2007). On an issue where the nonmoving party will bear the burden of proof at trial, the moving party may carry its initial burden of production by submitting admissible “evidence negating an essential element of the nonmoving party’s case,” or by showing, “after suitable discovery,” that the “nonmoving party does not have enough evidence of an essential element of its claim or defense to carry its ultimate burden of persuasion at trial.” Nissan Fire & Marine Ins. Co., Ltd. v. Fritz Cos., Inc., 210 F.3d 1099, 1106 (9th Cir. 2000); see also Celotex Corp. v. Catrett, 477 U.S. 317, 325 (1986) (“the burden on the moving party may be discharged by ‘showing’—that is, pointing out to the district court—that there is an absence of evidence to support the nonmoving party’s case”).

“Once the moving party meets its initial burden, the nonmoving party must go beyond the pleadings and, by its own affidavits or by the depositions, answers to interrogatories, and admissions on file, come forth with specific facts to show that a genuine issue of material fact exists.” Hansen v. United States, 7 F.3d 137, 138 (9th Cir. 1993) (per curiam). But allegedly disputed facts must be material—“the mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no *genuine* issue of *material* fact.” Anderson, 477 U.S. at 247–48. “When the nonmoving party relies only on its own affidavits to oppose summary judgment, it cannot rely on conclusory allegations unsupported by factual data to create an issue of material fact.” Hansen, 7

1 F.3d at 138.

2 When deciding a summary judgment motion, a court must view the evidence in the
3 light most favorable to the nonmoving party and draw all justifiable inferences in its favor.
4 Anderson, 477 U.S. at 255; Hunt v. City of Los Angeles, 638 F.3d 703, 709 (9th Cir.
5 2011). If evidence produced by the moving party conflicts with evidence produced by the
6 nonmoving party, the judge must assume the truth of the evidence set forth by the
7 nonmoving party with respect to that fact. See Tolan v. Cotton, 134 S. Ct. 1861, 1865
8 (2014); Leslie v. Grupo ICA, 198 F.3d 1152, 1158 (9th Cir. 1999). However, when a non-
9 moving party fails to produce evidence rebutting a defendant's showing, then an order for
10 summary adjudication is proper. Nissan Fire, 210 F.3d at 1103 ("If the nonmoving party
11 fails to produce enough evidence to create a genuine issue of material fact, the moving
12 party wins the motion for summary judgment.").

13 **B. Analysis**

14 Defendant's motion presents six main arguments: (1) all of plaintiff's claims must
15 fail because the factual record shows beyond reasonable dispute that a counterfeit
16 Thermage CPT device was used; (2) plaintiff's failure to warn claims fail; (3) plaintiff's
17 design defect claims fail; (4) plaintiffs manufacturing defect claim fails; (5) plaintiff's
18 warranty claims fail; and (6) plaintiff's prayer for punitive damages must be dismissed
19 because there is no clear and convincing evidence to support the claim. The court
20 addresses each in turn.

21 **1. Whether There Is a Genuine Dispute of Material Fact That an Authentic** 22 **Thermage CPT Device Was Used**

23 Starting with the preliminary issue, defendant argues that plaintiff has not provided
24 enough evidence to establish a genuine dispute of material fact that an authentic
25 Thermage CPT device was used. Defendant argues that plaintiff offers no physical
26 evidence that the device was in fact genuine and not counterfeit. Plaintiff argues that the
27 treating physician's deposition testimony is sufficient to create a disputed factual issue
28 and allow the jury to conclude that the machine was genuine. Plaintiff also offers

1 supporting expert testimony based on, inter alia, the pattern of plaintiff's injuries.

2 Defendant is correct that it cannot be liable for a product it did not manufacture,
3 control, or create. See Sindell v. Abbott Lab's, 26 Cal. 3d 588, 614–15 (1980) (“An
4 *essential* element of the plaintiff's cause of action for negligence, *or for that matter for any*
5 *other tort*, is that there be some reasonable connection between the act or omission of
6 the defendant and the damage which the plaintiff has suffered. . . . “[I]f recovery is sought
7 from a manufacturer, *it must be shown that he actually was the manufacturer of the*
8 *product which caused the injury*”).; see also Garcia v. Joseph Vince Co., 84 Cal. App. 3d
9 868, 874 (1978) (“there must first be proof that the defendant produced, manufactured,
10 sold, or was in some way responsible for the product”).

11 Defendant next argues that plaintiff must offer “direct identifying evidence such as
12 competent expert testimony, medical records, or other identifying physical or
13 documentary evidence to connect the device [to] Solta” to establish a dispute of material
14 fact and survive defendant's motion for summary judgment. Mot., Dkt. 117 at 10–11
15 (“Plaintiff must offer some ‘hard’ or direct identifying evidence to support her claim that
16 the device and components were authentic and manufactured by Solta.”). Defendant's
17 cited case law is largely non-binding and not persuasive on this point, and the cited
18 California case law supports the opposite conclusion. See, e.g., Collin v. CalPortland
19 Co., 228 Cal. App. 4th 582, 590 (2014) (not requiring “hard” evidence, but rather
20 assessing specific contentions in witness testimony). Solta also discusses Garcia v.
21 Joseph Vince at some length. In that case, a fencer suffered an eye injury when the
22 opponent's sabre pierced his face mask. In identifying the offending weapon, the plaintiff
23 had “established only that the blade was made and supplied by either (a) American or by
24 (b) Vince, not by both; but which one of the two was unknown.” Garcia, 84 Cal. App. 3d
25 at 873–74. That is because the testifying witnesses in that action “could not recall
26 whether at the time he used his own or a school blade, and both he and school
27 purchased from both defendants.” Id. at 874. Another witness “was also unable to say
28 from which source the blade came.” Id. Contrary to plaintiff's argument that the court

1 rejected all witness testimony and required physical evidence, the court instead assessed
 2 the witness testimony in detail and reasoned that the testimony was—even if believed
 3 entirely on its own terms—insufficient to identify the defendant as the manufacturer. The
 4 witness testimony that the court assessed and relied on “was evenly divided as to who
 5 possibly could have been the supplier of the blade.” Id.

6 In the present case although the device used was not produced nor was its serial
 7 number captured in the medical records, plaintiff’s treating physician unambiguously
 8 testified that he used a genuine Thermage CPT device on plaintiff. Prior to treating
 9 plaintiff, Dr. Huang estimated that he had provided Thermage CPT treatments on
 10 average once or twice per week for two years. Huang Dep., Dkt. 131-1, Ex. 4 at 29:16-
 11 30:6. When asked if the Thermage CPT device he used during plaintiff’s procedure
 12 looked the same as other Thermage CPT devices he had used in the past, Dr. Huang
 13 testified that “[i]n terms of the appearance of the device and as far as to the aspects that I
 14 could see, yes, they are the same.” Id. at 31:21-32:2. Dr. Huang was then shown
 15 pictures from the Thermage CPT user manual and confirmed that the device he used
 16 during plaintiff’s procedure had the same system panel, casing, buttons, user interface,
 17 handpiece, treatment tip, coupling fluid, cryogen canister, and “Thermage” logo as shown
 18 in the manual. Id. at 32:16-35:9. Dr. Huang further testified: “The device has a very
 19 unique appearance. I think at that time there were all -- no other device that had a similar
 20 appearance.” Id. at 35:25-36:2. Additionally, the record contains medical records which
 21 noted that a Thermage device was used in plaintiff’s procedure. See Pollack Decl.,
 22 Dkt. 138, Ex. 5 at ECF pp. 546–50 & 556–59.

23 Plaintiff does not seek summary judgment and still must prove at trial that the
 24 device was manufactured by Solta, and Solta is free to try to prove otherwise. However,
 25 Dr. Huang’s testimony along with the notation in the medical record are sufficient to
 26 create a triable issue of material fact as to the authenticity of the device used. Hence,
 27 defendant’s motion for summary judgment on this basis is DENIED.

28 **2. Plaintiff’s Strict Liability and Negligent Failure to Warn Claims**

Plaintiff's third cause of action is for strict liability failure to warn, and her fourth cause of action is for negligent failure to warn. SAC ¶¶ 115(d)–(g). Defendant seeks summary judgment on both causes of action. Plaintiff confirmed at the hearing that there is no garden variety negligence cause of action; rather the negligence cause of action pertains to the design defect, manufacturing defect, and failure to warn causes of action.

a. Legal Standard

Strict liability for failure to warn requires the plaintiff to prove the following: “(1) the defendant manufactured, distributed, or sold the product; (2) the product had potential risks that were known or knowable at the time of manufacture or distribution, or sale; (3) that the potential risks presented a substantial danger to users of the product; (4) that ordinary consumers would not have recognized the potential risks; (5) that the defendant failed to adequately warn of the potential risks; (6) that the plaintiff was harmed while using the product in a reasonably foreseeable way; (7) and that the lack of sufficient warnings was a substantial factor in causing the plaintiff's harm.” Rosa v. City of Seaside, 675 F.Supp.2d 1006, 1011 (N.D. Cal. 2009) (quoting Jud. Council of Cal. Civ. Jury Instruction No. 1205).

With respect to a known or knowable risk, the plaintiff must prove that “the defendant did not adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.” Id. at 1012.

“The purpose of requiring adequate warnings is to inform consumers about a product's hazards and faults of which they are unaware, so that the consumer may then either refrain from using the product altogether or avoid the danger by careful use.” Taylor v. Elliott Turbomachinery Co., 171 Cal. App. 4th 564, 577 (2009); see also Anderson v. Owens-Corning Fiberglas Corp., 53 Cal. 3d 987, 1003 (1991) (“the user of the product must be given the option either to refrain from using the product at all or to use it in such a way as to minimize the degree of danger”). On the other hand, “[t]here is no duty to warn of known risks or obvious dangers.” Chavez v. Glock, Inc., 207 Cal. App.

4th 1283, 1304 (2012); accord Carlin v. Superior Court, 13 Cal. 4th 1104, 1116 (1996) (“a pharmaceutical manufacturer may not be required to provide warning of a risk known to the medical community”).

A claim for negligent failure to warn requires a plaintiff to prove that: “(1) the defendant manufactured, distributed, or sold the product; (2) the defendant knew or reasonably should have known that the product was dangerous or was likely to be dangerous when used in a reasonably foreseeable manner; (3) the defendant knew or reasonably should have known that users would not realize the danger; (4) the defendant failed to adequately warn of the danger or instruct on the safe use of the product; (5) a reasonable manufacturer, distributor, or seller under the same or similar circumstances would have warned of the danger or instructed on the safe use of the product; (6) the plaintiff was harmed; and (7) the defendant's failure to warn or instruct was a substantial factor in causing the plaintiff's harm.” Rosa, 675 F.Supp.2d at 1011–12 (quoting Jud. Council of Cal. Civ. Jury Instruction No. 1222).

This claim “requires a plaintiff to prove that a manufacturer or distributor did not warn of a particular risk for reasons which fell below the acceptable standard of care, i.e., what a reasonably prudent manufacturer would have known and warned about.” Anderson, 53 Cal. 3d at 1002; see also Chavez, 207 Cal. App. 4th at 1305. A “reasonable manufacturer would not be charged with knowing more than what would come to light from the prevailing scientific and medical knowledge.” Valentine v. Baxter Healthcare Corp., 68 Cal. App. 4th 1467, 1483–84 (1999). A manufacturer might, for example, prevail against a negligence claim where it decided a risk of harm was not so great as to require a warning based on its own testing that showed a result contrary to that of others in the scientific community. Anderson, 53 Cal. 3d at 1003.

The California Supreme Court has provided the following explanation of the differences between a strict liability and negligent failure to warn claim:

[F]ailure to warn in strict liability differs markedly from failure to warn in the negligence context. Negligence law in a failure-to-warn case requires a plaintiff to prove that a manufacturer or

distributor did not warn of a particular risk for reasons which fell below the acceptable standard of care, i.e., what a reasonably prudent manufacturer would have known and warned about. Strict liability is not concerned with the standard of due care or the reasonableness of a manufacturer's conduct.... [I]n strict liability, as opposed to negligence, the reasonableness of the defendant's failure to warn is immaterial.

Anderson, 53 Cal. 3d at 1002–03 (footnote omitted).

For both claims, a manufacturer of a prescription drug is obligated to warn physicians, not patients, of potential side effects associated with its pharmaceutical products. Motus v. Pfizer Inc., 358 F.3d 659, 661 (9th Cir. 2004) (“Motus II”) (pharmaceutical manufacturer “is obligated to warn doctors, not patients, of potential side-effects”). Known as the “learned intermediary” doctrine, the duty to warn the physician rather than the patient also applies to prescription implants. Valentine, 68 Cal. App. 4th at 1483 (“In the case of prescription drugs and implants, the physician stands in the shoes of the ‘ordinary user’ because it is through the physician that a patient learns of the properties and proper use of the drug or implant.”). A manufacturer discharges its duty to warn if it provides an adequate warning to the physician, regardless of whether the warning reaches the patient. Motus v. Pfizer Inc., 196 F. Supp. 2d 984, 991 (C.D. Cal. 2001) (“Motus I”), aff’d sub nom. Motus II, 358 F.3d at 659. Although this case involves neither a prescription drug nor an implant, both parties agree that this standard should also apply to the medical device used by a medical professional in this case.

Both claims require a plaintiff to demonstrate that the defendant failed to adequately warn of the danger of the product. “Interpretation of the adequacy of the written language of a warning is a question of law which can be decided on summary judgment.” Dash v. Roche Lab., 74 F.3d 1245 (9th Cir. 1996); Temple v. Velcro USA, Inc., 148 Cal. App. 3d 1090, 1095 (1983) (“proper for the court in a motion for summary judgment to determine the adequacy of the warning language as a matter of law”). “Whether a warning is adequate depends on ‘how a prescribing doctor would understand the label.’” Rodman v. Otsuka Am. Pharm., Inc., 564 F. Supp. 3d 879, 891 (N.D. Cal. 2020), aff’d, No. 20-16646, 2021 WL 5850914 (9th Cir. Dec. 9, 2021) (quoting Hexum v.

Eli Lilly & Co., 2015 WL 5008263 at *7 (C.D. Cal. 2015)). There can be no genuine dispute about the adequacy of a warning that “directly warns in plain and explicit terms of the specific risk that has caused injury to the plaintiff.” Id. (quoting Utts v. Bristol-Myers Squibb Co., 251 F. Supp. 3d 644, 673-74 (S.D.N.Y. 2017) (applying California law)); see also Dash, 74 F.3d at 1245 (“A written warning is adequate if it directly warns in plain and explicit terms of the specific risk that has caused injury to plaintiff.”) (citing Kearl v. Lederle Lab'ys, 172 Cal. App. 3d 812, 834 (1985)).

Both claims require plaintiff to demonstrate that the defendant's failure to warn or instruct was a substantial factor in causing the plaintiff's harm. A plaintiff must prove that “that the inadequacy or absence of the warning caused the plaintiff's injury.” Motus I, 196 F. Supp. 2d at 991. “[A] product defect claim based on insufficient warnings cannot survive summary judgment if stronger warnings would not have altered the conduct of the prescribing physician.” Motus II, 358 F.3d at 661.

b. Solta's Warnings for The Thermage CPT

Solta argues that plaintiff's failure to warn claim fails as a matter of law because the prescribing physician was actually aware of the risks plaintiff identifies. It argues that plaintiff's claims must fail because she cannot prove that the warnings given to Dr. Huang were actually inadequate. Mot. at 19–20. Solta argues that it adequately warned Dr. Huang specifically of the potential adverse events of second-degree burns and painful blisters from the treatment in the Thermage CPT Manual. Plaintiff argues that the adequacy of Solta's warnings is a question of fact for the jury because the user manual was vague and ambiguous about the risk of burn injuries when treatment was coupled with general anesthesia or other devices used during the same treatment session.

i. General Anesthesia

The Thermage CPT's user manual includes a list of potential adverse patient reactions, which include Burns, Blisters, Scabbing, and Scarring. See Steele Decl., Dkt. 127, Ex. A (“Manual”) at 18 (“The procedure may produce heating in the upper layers of the skin, causing burns and subsequent blister and scab formation. There is a small

1 chance of scar formation.”). Furthermore, it is an undisputed fact that Dr. Huang was
2 actually aware of the risk of burns and resulting blisters, among other possible adverse
3 events associated with Thermage CPT treatment. See Huang Dep. at 90:8-93:1 (“Q. Dr.
4 Huang, what were the risks of performing Thermage CPT treatment that you knew about
5 before performing Ms. Lin's procedure in January of 2019? A. As far as I know, there
6 could be burns that will result in blisters. Maybe some open wounds, some bruises and
7 swelling.”). Dr. Huang had read at least one version of the product manual that explained
8 those risks, and he understood them. Id. at 119:16-124:25; 109:7-111:10 (Dr. Huang
9 read all pages of the 2010 Thermage CPT manual).

10 Dr. Huang also testified that he was aware of the risk of burn injuries during a
11 Thermage CPT treatment specifically when performed under general anesthesia. He
12 testified that general anesthesia is “not part of [his] general practice” and that he “would
13 advise patients against general anesthesia.” Id. at 44:11–16. Dr. Huang testified that he
14 “actually advised her [plaintiff] against it [general anesthesia]” and he “informed her [of]
15 the risks associated with it.” Id. at 45:1–12; see also id. at 96:24–97:7 (“I also explained
16 to her because she would be under general anesthesiology, so -- anesthesia, so the
17 energy level that she wants to use is higher and there could be the risk associated with
18 that.”). Dr. Huang acknowledged awareness of the particular risks of using general
19 anesthesia during treatment, testifying that, “[t]he risk of burn has more to do with energy
20 level. It doesn't have to do with the anesthesia. But because after the anesthesia
21 treatment, the patient's pain tolerance level is higher; so if the energy level is high, there
22 could be a risk of burn.” Id. at 94:5-95:19. Dr. Huang also had plaintiff sign a Consent
23 For Thermage Treatment form, which identified the risk of burns when Thermage CPT is
24 performed under general anesthesia, specifically indicating that the risk comes from an
25 increased dosage or intensity of treatment: “During the Thermage treatment, I agree to
26 carry out general anesthesia (IVS). General anesthesia can increase the dosage, but a
27 small number of people are at risk of burns.” See id. at 93:2–94:22; see also Steele
28 Decl., Dkt. 127, Ex. E at Bates No. LIN000151.

1 This uncontested evidence demonstrates that Dr. Huang was actually aware of the
2 precise risk that plaintiff raises in her failure-to-warn claim, and even the precise
3 mechanism by which that risk operates. Specifically, he was aware of the risk of burns
4 and blisters generally with use of the device. Moreover, he was aware that the risk
5 increased with *general anesthesia* because the “patient’s pain tolerance level is higher”
6 such that “if the energy level is high, there could be the risk of burn”. Huang Dep. at
7 94:15-95:6 (discussing general anesthesia).

8 Plaintiff argues that the instruction manual “was vague and ambiguous about the
9 risk of burn injuries caused by the use of sedation and general anesthesia” because it
10 suggested that the primary risk of anesthesia was in changing “the electrical resistance of
11 the patient’s skin tissue and therefore impact the heating profile of the skin.” Opp.,
12 Dkt. 131 at 21. But Dr. Huang’s testimony directly demonstrates that he was aware that
13 the risk from general anesthesia was different. He knew that “[i]t doesn’t have to do with
14 the anesthesia” but instead “has more to do with energy level [give than] the
15 patient’s pain tolerance level is higher.” Huang Dep. at 94:15-95:6.

16 Plaintiff argues that a doctor reading the warning section about anesthesia could
17 reasonably conclude that anesthesia is safe to use so long as it is not injected. And
18 although plaintiff’s opposition speculates as to various potential reasons a doctor might
19 misunderstand Solta’s warnings, the treating physician in this case made clear that he in
20 fact understood the warnings perfectly well.

21 California requires Solta to warn the learned intermediary about certain risks of its
22 prescription device. The uncontested evidence presented to this court unambiguously
23 shows that Solta did so.

24 Plaintiff argues that Solta’s warning was not enough even if Dr. Huang was
25 actually aware of the risk. Instead, plaintiff asks the court to find that any warning short of
26 a complete contraindication or ban is insufficient as a matter of law. But “[t]he purpose of
27 requiring adequate warnings is to inform consumers about a product’s hazards and faults
28 of which they are unaware, so that the consumer may then either refrain from using the

product altogether or avoid the danger by careful use.” Taylor, 171 Cal. App. 4th at 577; see also Anderson, 53 Cal. 3d at 1003. Plaintiff’s theory would require the jury to go beyond what is permitted by California law and find that a defendant must not only inform but also explicitly limit the usage of a product, thereby eliminating the consumer’s option to “avoid the danger by careful use.” Taylor, 171 Cal. App. 4th at 577.

Plaintiff’s claims face an additional problem, as each claim requires that the alleged lack of sufficient warning was a substantial factor in causing the plaintiff’s harm. See Rosa, 675 F.Supp.2d at 1011–12; Motus I, 196 F.Supp.2d at 991 (“A plaintiff asserting causes of action based on a failure to warn must prove not only that no warning was provided or the warning was inadequate, but also that the inadequacy or absence of the warning caused the plaintiff’s injury.”).

“A plaintiff cannot prove that an allegedly inadequate warning was the proximate cause of his or her injury where the treating physician knew of the risk at issue.” Thompson v. Janssen Pharms., Inc., No. CV162628PSGAGRX, 2017 WL 5135548, at *8 (C.D. Cal. Oct. 23, 2017), aff’d, 756 F. App’x 740 (9th Cir. 2019) (citing Plummer v. Lederle Lab’ys, Div. of Am. Cyanamid Co., 819 F.2d 349, 359 (2d Cir. 1987) (applying California law and concluding that “no one needs notice of that which he already knows”)). Accordingly, even if the warnings were inadequate, plaintiff has not demonstrated a material question of fact with respect to causation because the uncontested evidence demonstrates that the treating physician knew of the risk at issue.

As discussed above, Dr. Huang confirmed that he was aware that the Thermage CPT could cause burns, and that the risk was specifically elevated when the patient was under general anesthesia because an increased pain threshold affected the patient’s ability to provide feedback. More explicit warnings with respect to the risks (short of an absolute ban against the use of anesthesia) would not have altered Dr. Huang’s conduct, as he was already adequately aware of the risks. Plaintiff has presented no reason to believe that any such warnings would have altered Dr. Huang’s treatment. “[A] product defect claim based on insufficient warnings cannot survive summary judgment if stronger

warnings would not have altered the conduct of the prescribing physician.” Motus II, 358 F.3d at 661. Accordingly, plaintiff has not established a dispute of material fact with respect to causation for her failure to warn claims based on the use of anesthesia.

ii. Dual-Device Use With Ultherapy Treatment

Plaintiff’s procedure also involved Dr. Huang’s use of two devices. First, the doctor used an Ulthera device (the Ulthera device performs a procedure referred to as “Ultherapy”) on plaintiff’s face, which heated her skin. Second, he used the Thermage CPT device, which heated it more. Using devices serially in that manner is referred to by the parties as a “dual device” treatment. Plaintiff argues that defendant should have issued a warning about the enhanced risk of using the Thermage CPT in conjunction with other similar procedures that heat the skin, like the Ulthera device.

The treating physician Dr. Huang testified that, at the time, he was aware that using the Ulthera device carried risks of burns, bruises, temporary nerve damage, scarring, and blistering “because it’s also [a] heat-related treatment”. Huang Dep. at 87:20–88:1. He also informed plaintiff “prior to the procedure what could be the risks when the . . . Ulthera is performed together with Thermage.” Id. at 88:22–89:2; see also id. at 96:24–97:7. He confirmed that “it was not my idea to combine these two treatments at the same time.” Id. at 54:8–9.

The relevant risk of using two devices serially is enhanced heat. As described above, Solta thoroughly warned doctors about the risks of excessive heat. However, there is no warning specifically about greater risk when *a different medical device* has already enhanced the skin’s heat. Plaintiff argues that failing to specifically warn that another medical device—or perhaps specifically the Ulthera—enhances the risk of injury constituted a failure to adequately warn plaintiff’s learned intermediary, Dr. Huang. But plaintiff asks too much by proposing that defendant must warn with specificity about every conceivable element that might enhance the heat of a patient’s skin prior to or during a Thermage CPT treatment. Here, the warnings with respect to heat were sufficient. Moreover Dr. Huang knew that heat was the ultimate risk, and he knew that

1 using the Ulthera device prior to the Thermage CPT device would elevate the heat of
2 plaintiff's skin. Contrary to plaintiff's position, every possible reason that heat might be
3 increased need not be identified with particularity to adequately warn a learned
4 intermediary.

5 For the foregoing reasons, defendant's motion for summary judgment is
6 GRANTED with respect to plaintiff's failure to warn claims based on both strict liability
7 and negligence.

8 **3. Plaintiff's Design Defect Claims**

9 Plaintiff's first cause of action asserts a claim for strict liability design defect. Her
10 fourth cause of action for negligence includes allegations of negligent design.

11 Solta argues that (1) the claim fails under the risk-benefit test; and (2) plaintiff has
12 not met her burden to demonstrate a design defect caused her burns, as the risk of burns
13 is a generally known risk associated with the procedure that she consented to.

14 Plaintiff argues that she met her burden under both the consumer expectation test
15 and the risk-benefit test because (1) she proposes a new design feature where the
16 device would measure subsurface skin temperature and automatically cap energy levels;
17 (2) there was a design defect in relying on patient feedback because she was under
18 anesthesia and could not provide feedback; and (3) under the consumer expectation test,
19 consumers would not expect to be burned.

20 **a. Legal Standard**

21 Under California Law, a design can be found defective under a strict liability theory
22 in one of two ways. "[A] product is defective in design either (1) if the product has failed
23 to perform as safely as an ordinary consumer would expect when used in an intended or
24 reasonably foreseeable manner, or (2) if, in light of the relevant factors... the benefits of
25 the challenged design do not outweigh the risk of danger inherent in such design."

26 Barker v. Lull Engineering Co., 20 Cal. 3d 413, 418 (1978). "Risk-benefit and consumer
27 expectation are alternative theories for establishing a cause of action for design defect
28 strict liability". Chavez, 207 Cal. App. 4th at 1312. For both negligent and strict liability

1 design defect claims, the plaintiff must prove a defect in the device's design caused her
2 injury. Merrill v. Navegar, Inc., 26 Cal. 4th 465, 479 (2001); Soule v. Gen. Motors Corp.,
3 8 Cal. 4th 548, 550 (1994) (a causal connection between the alleged defective design
4 and its failure is necessary).

5 The consumer expectation test is reserved for cases in which the "everyday
6 experience of the product's users permits a conclusion that the product's design violated
7 minimum safety assumptions, and is thus defective regardless of expert opinion about
8 the merits of the design." Soule, 8 Cal. 4th at 567. On the other hand, the consumer
9 expectations test is not appropriate "when the ultimate issue of design defect calls for a
10 careful assessment of feasibility, practicality, risk, and benefit." Id. at 562; see also Lucas
11 v. City of Visalia, 726 F. Supp. 2d 1149, 1154–55. (E.D. Cal. 2010).

12 Under the risk-benefit test, a product is defective if the design embodies
13 "excessive preventable danger", or in other words if "the risk of danger inherent in the
14 challenged design outweighs the benefits of such design." Barker, 20 Cal. 3d at 430;
15 accord Lucas, 726 F. Supp. 2d at 1154. In making this determination, a jury may
16 consider, among other relevant factors, "the gravity of the danger posed by the
17 challenged design, the likelihood that such danger would occur, the mechanical feasibility
18 of a safer alternative design, the financial cost of an improved design, and the adverse
19 consequences to the product and to the consumer that would result from an alternative
20 design." Barker, 20 Cal. 3d at 431.

21 The risk-benefit test first requires the plaintiff to make a prima facie showing that
22 his or her injury was caused by the product's defective design. Second, the burden shifts
23 to the defendant to establish that the product is not defective. Thus, under the risk-
24 benefit test, a product may be found defective in design "if the plaintiff demonstrates that
25 the product's design proximately caused [her] injury and the defendant fails to establish,
26 in light of the relevant factors, that, on balance, the benefits of the challenged design
27 outweigh the risk of danger inherent in such design." Id. at 432.

28 In cases where the plaintiff alleges defective design due to the manufacturer's

1 failure to provide “a particular safety device” or feature that would have prevented the
 2 injury, such a claim “presents a factual issue which can only be resolved by the trier of
 3 fact” absent “very unusual circumstances.” Campbell v. General Motors Corp., 32 Cal.
 4 3d 112, 120 (1982).

5 A design defect claim under a negligence theory must prove the additional
 6 element “that the defect in the product was due to negligence of the defendant.” Chavez,
 7 207 Cal. App. 4th at 1305. As with a general negligence claim, the plaintiff must also
 8 show breach of duty, causation, and damages. See Howard v. Omni Hotels Mgmt.
 9 Corp., 203 Cal. App. 4th 403, 428 (2012). Therefore, a product is not negligently
 10 designed so long as “the manufacturer took reasonable precautions in an attempt to
 11 design a safe product or otherwise acted as a reasonably prudent manufacturer would
 12 have under the circumstances.” Barker, 20 Cal. 3d at 434.

13 **b. Analysis**

14 **i. Strict Liability**

15 Defendant argues that (A) the consumer expectations test is inapplicable to this
 16 case; and (B) plaintiff has not offered evidence demonstrating that the design of the
 17 Thermage CPT creates excessively preventable danger under the risk-benefit test.
 18 Plaintiff argues that she has demonstrated a triable issue of fact under both tests.

19 **(A) The Consumer Expectations Test**

20 “[T]he consumer expectations test is reserved for cases in which the *everyday*
 21 *experience* of the product's users permits a conclusion that the product's design violated
 22 *minimum* safety assumptions, and is thus defective *regardless of expert opinion about*
 23 *the merits of the design.*” Soule, 8 Cal. 4th at 556–67 (“The trial court erred by giving an
 24 ‘ordinary consumer expectations’ instruction in this complex case.”). Accordingly, “the
 25 consumer expectations test is properly applied in cases in which the *everyday experience*
 26 of the product's users permits a conclusion that the product's design violated *minimum*
 27 safety assumptions, and is thus defective *regardless of expert opinion about the merits of*
 28 *the design.* In contrast, the test should not be used when the ultimate issue of design

1 defect calls for a careful assessment of feasibility, practicality, risk, and benefit, since in
 2 many instances it is simply impossible to eliminate the balancing or weighing of
 3 competing considerations in determining whether a product is defectively designed or
 4 not.” Jones v. John Crane, Inc., 132 Cal. App. 4th 990, 1002 (2005) (internal quotation
 5 marks omitted) (quoting Soule, 8 Cal. 4th at 562–63, 567).

6 Critically, “the jury may not be left free to find a violation of ordinary consumer
 7 expectations whenever it chooses. Unless the facts actually permit an inference that the
 8 product's performance did not meet the minimum safety expectations of its ordinary
 9 users, the jury must engage in the balancing of risks and benefits required by the [risk-
 10 benefit test]. Accordingly, as Barker indicated, instructions are misleading and incorrect if
 11 they allow a jury to avoid this risk-benefit analysis in a case where it is required.” Soule,
 12 8 Cal. 4th at 568. “[W]hen the ultimate issue of design defect calls for a careful
 13 assessment of feasibility, practicality, risk, and benefit, the case should not be resolved
 14 simply on the basis of ordinary consumer expectations.” Id. at 562 & 567 (“In such
 15 cases, the jury *must* consider the manufacturer's evidence of competing design
 16 considerations, and the issue of design defect cannot fairly be resolved by standardless
 17 reference to the ‘expectations’ of an ‘ordinary consumer.’” (citation omitted)).

18 Here, the prescription-only Thermage CPT device is used only by specialized
 19 physicians and trained medical professionals, and “[t]he purposes, behaviors, and
 20 dangers of” the product are not are not “commonly understood” by ordinary consumers
 21 likely to makeup a jury. Id. at 566. Without ordinary knowledge of the product’s
 22 characteristics, lay consumers cannot have “reasonable, widely accepted minimum
 23 expectations about the circumstances under which it should perform safely.” Id.
 24 Accordingly, the jury can be presented only with the risk-benefit test, and shall not be
 25 permitted to resolve the claim using the consumer expectations test.

26 (B) The Risk-Benefit Test

27 Defendant argues that there is no dispute of material fact concerning whether the
 28 Thermage CPT creates excessively preventable danger under the risk-benefit test.

1 Defendant argues that is the case because the actual rate of adverse event reports
2 involving burns occur in only 0.007% of treatments, which is a figure demonstrating an
3 acceptable standard of care. Plaintiff counters that the device cannot measure the
4 temperature of subsurface skin, so it relies exclusively on patient feedback about the
5 extent of her pain and discomfort during the procedure to inform the user about the
6 proper energy level. That design is inherently flawed, and an alternative design where
7 the device measured subsurface skin temperature and adjusted power levels
8 automatically would be safer.

9 Under the risk-benefit test, the court first assesses whether plaintiff has made a
10 prima facie showing that her injury was caused by the product's defective design. Here,
11 plaintiff has identified the design fault as the device's reliance on the patient's subjective
12 pain reporting rather than an objective temperature measurement. Capping the device's
13 temperature based on an objective measure of subsurface skin temperature would likely
14 have prevented her injury—a point that defendant does not contest. Plaintiff has
15 accordingly satisfied her burden to present a prima facie showing.

16 The court next assesses whether defendant has established that the product is not
17 defective, which means "that, on balance, the benefits of the challenged design outweigh
18 the risk of danger inherent in such design." Barker, 20 Cal. 3d at 432. In making this
19 determination, the court looks to, among other relevant factors, "the gravity of the danger
20 posed by the challenged design, the likelihood that such danger would occur, the
21 mechanical feasibility of a safer alternative design, the financial cost of an improved
22 design, and the adverse consequences to the product and to the consumer that would
23 result from an alternative design." Id. at 431.

24 Defendant presents uncontroverted evidence that only 0.007% of treatments result
25 in burns. But defendant does not provide any authority indicating that any particular rate
26 of harm is sufficient to resolve a factual dispute about whether the benefits of the
27 challenged design outweigh the risk of danger inherent in such design at the summary
28 judgment stage. The question is whether the current design correctly balances tradeoffs.

Defendant's figure showing that burns are rare certainly is relevant to that question, but it does not remove the factual dispute as to whether the tradeoff is correctly balanced. Defendant rests on that figure almost entirely, and it fails to address other factors such as the mechanical feasibility of a safer alternative design, the financial cost of an improved design, or the adverse consequences to the product and to the consumer that would result from an alternative design. See generally id. at 431 ("the burden should appropriately shift to the defendant to prove, in light of the relevant factors, that the product is not defective"); Demara v. The Raymond Corp., 13 Cal. App. 5th 545, 563 (2017) ("In such a case, expert testimony is required."); Gonzalez v. Autoliv ASP, Inc., 154 Cal. App. 4th 780, 787 (2007) (defendant must provide "evidence that the benefits of the design outweigh its inherent risks [which is] necessary to show the absence of a design defect, a burden carried by the defendant").

This reasoning is in line with California courts' general position on such claims and their caution that the weighing of these factors is normally the proper province of the jury:

Where the plaintiff in a strict liability action introduces evidence that she was injured while using the product in an intended or reasonably foreseeable manner and an attempt to avoid injury was frustrated by the absence of a particular safety device, the jury should be given the opportunity to determine whether the facts necessary to impose liability have been established. This is particularly true where the injury which occurred is precisely the sort which the safety device is designed to prevent. The policies behind the rule of strict products liability favor jury resolution whenever the evidence can be interpreted to support plaintiff's position.

Campbell, 32 Cal. 3d at 126.

Even though Solta issued warnings about the use of anesthesia and the treating doctor knew of the risks, such use was still reasonably foreseeable. Accordingly, the jury is the proper entity to determine what mix of design changes may or may not have been appropriate in light of the risk of burns. And Solta will have the opportunity at that time to present its evidence showing that burns are quite rare indeed and that potential misuse of the device by the doctor may be the cause of the injury.

Accordingly, defendant's motion for summary judgement is DENIED with respect

1 to plaintiff's strict liability design defect cause of action, which may proceed based on the
2 risk-benefit test but not the consumer expectation test.

3 **ii. Negligence**

4 A design defect claim under a negligence theory must prove the additional
5 element "that the defect in the product was due to negligence of the defendant." Chavez,
6 207 Cal. App. 4th at 1305. As with a general negligence claim, the plaintiff must also
7 show breach of duty, causation, and damages. See Howard, 203 Cal. App. 4th at 428.
8 Therefore, a product is not negligently designed so long as "the manufacturer took
9 reasonable precautions in an attempt to design a safe product or otherwise acted as a
10 reasonably prudent manufacturer would have under the circumstances." Barker, 20 Cal.
11 3d at 434.

12 Solta argues that plaintiff failed to present any evidence that Solta did not take
13 reasonable precautions in designing a safe product. Mot. at 24. Plaintiff argues that the
14 product was unreasonably designed given the risk of burn injuries and the low efficacy of
15 the device, that it would have been feasible to include features that prevented this type of
16 injury, and that Solta knew since at least 2004 (5 years before the product's release) that
17 it was unsafe to use "IV sedation, nerve blocks, and other unconscious or 'twilight'
18 sedation techniques" during Thermage treatment. Opp. at 8. She argues that despite
19 this knowledge, and the common industry knowledge that doctors were using similar
20 products with sedation, Solta did not include safety features in the design to prevent
21 burning.

22 These facts are sufficient to establish a disputed issue of material fact, and
23 accordingly, defendant's motion for summary judgement is DENIED with respect to
24 plaintiff's negligent design defect cause of action.

25 **4. Plaintiff's Manufacturing Defect Claims**

26 Plaintiff does not oppose defendant's motion with respect to her manufacturing
27 defect claims. Accordingly, the court GRANTS defendant's motion with respect to both
28 strict liability and negligent manufacturing causes of action.

5. Plaintiff's Express and Implied Warranty Claims

Plaintiff does not oppose defendant's motion with respect to her express and implied warranty claims. Accordingly, the court GRANTS defendant's motion with respect to those causes of action.

6. Plaintiff's Prayer for Punitive Damages

Solta argues that punitive damages are not available where a manufacturer warns of the potential risk that results in a plaintiff's injury. It argues that plaintiff has not established any evidence, let alone clear and convincing evidence, of malice, oppression, or fraud. Plaintiff argues that the factual record demonstrates Solta's conscience disregard for human safety because it knew about the risks of its product and failed to correct—or even intentionally obscured—them.

At this stage of proceedings, the court declines to eliminate plaintiff's prayer of punitive damages. The factual record presents disputed questions of fact as to plaintiff's eligibility for the remedy that are more appropriately resolved by a jury after hearing the parties' trial presentations. Accordingly, the motion is DENIED with respect to defendant's request to prohibit plaintiff from seeking punitive damages at trial.

CONCLUSION

For the foregoing reasons, defendant's motion is GRANTED IN PART AND DENIED IN PART. Defendant's motion for summary judgment on the failure of plaintiff to prove the authenticity of the device is DENIED. Defendant's motion for summary judgment on plaintiff's strict liability and negligent failure to warn causes of action (3 & 4) is GRANTED. Defendant's motion for summary judgment on plaintiff's strict liability and negligent design defect causes of action (1 & 4) is DENIED. Defendant's motion for summary judgment on plaintiff's strict liability and negligent manufacturing defect, express warranty, and implied warranty causes of action (2, 5, 6) is GRANTED. Defendant's motion for summary judgment on plaintiff's prayer for punitive damages is DENIED.

Rulings on the Daubert and sealing motions will follow in separate orders.

IT IS SO ORDERED.

Dated: December 18, 2024

/s/ Phyllis J. Hamilton

PHYLLIS J. HAMILTON
United States District Judge